Dr. Daniel Griffin's Clinical treatment summary for 11/09/2022

Clinical Course/Treatment – Polio

Polio Vaccine

Adults who are unvaccinated or without any documentation of previous polio vaccination should be given three doses of IPV at these recommended intervals:

1. Two doses separated by 1 to 2 months
2. A third dose 6 to 12 months after the second dose

Clinical Course/Treatment – Monkeypox

MPX CLINCIAL COURSE/TREATMENT: Observation or in some cases TPOXX or if eye involvement VIROPTIC eye drops (trifluridine)

VACCINATION:
People who meet **all** of the following criteria are eligible to be vaccinated:

- Are a gay, bisexual, or other man who has sex with men and/or are transgender, gender non-conforming, or gender non-binary;
- Are age 18 or older, and;
- Have had multiple or anonymous sex partners in the last 14 days

This is the **A5418:Study Of Tecovirimat For Human Monkeypox Virus (STOMP)**

Study Description

The study of Tecovirimat for treatment of human Monkeypox (STOMP) is a NIAID-funded clinical trial led by the ACTG to evaluate the effectiveness of the antiviral tecovirimat, also known as TPOXX, for the treatment of human Monkeypox infection.

Who can join?

Adults and children of any age with Monkeypox are eligible to enroll in this trial. See list of participation sites below.

What do I need to do in the study?

Step 1: daily self skin checks and photographs
Step 2: participant reports clinical resolution
Step 3: video visit to confirm clinical resolution
Step 4: confirmation at in person visit

What treatments or drugs are involved with this study?

Tecovirimat, manufactured by the pharmaceutical company SIGA Technologies, Inc. (New York), is approved by the FDA for the treatment of smallpox. The drug prevents the virus from spreading in the body

by preventing virus particles from existing human cells by targeting a portion found on both the variola virus, which causes smallpox, and the monkeypox virus.

Duration of Study

57 days

For more information, please visit https://www.stomptpoxx.org/main

Columbia will be one of the sites and my friend Jason Zucker is helping us here enroll patients. Not just severe.

https://www.nih.gov/news-events/news-releases/us-clinical-trial-evaluating-antiviral-monkeypox-begins

Clinical Course/Treatment – COVID

PASSIVE VACCINATION- EvuSheld.

Authorized for use in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination(s).

For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

https://www.fda.gov/media/154701/download

POST-EXPOSURE PERIOD

https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html

Early Viral Upper Respiratory Non-hypoxic phase – https://www.covid.gov

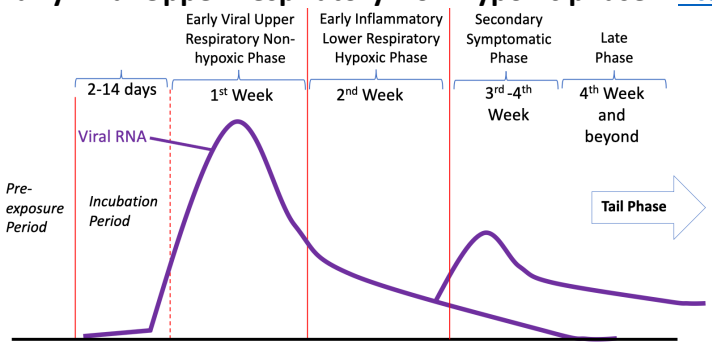

Figure 1. Time course of COVID-19 divided into the two preclinical periods, the Pre-exposure Period and the Incubation Period, followed by four clinical phases, the Early Viral Upper Respiratory Non-hypoxic Phase, the Early Inflammatory Lower Respiratory Hypoxic Phase, the Secondary Symptomatic Phase and the Late Phase.

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1-Paxlovid – with an 89-88% reduction in progression if given in the first 3-5 days. We have many resources the **PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers** and https://www.fda.gov/media/158165/download

- **Paxlovid** (89-88% reduction in progression if given in the first 3-5 days)
    - https://www.fda.gov/media/155051/download
    - https://www.fda.gov/media/158165/download
  - https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
  - https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com
  - https://www.covid19-druginteractions.org/checker and https://www.idsociety.org/paxlovid

2 -Remdesivir (the order changed!) -we have the 3-day early IV data suggesting an 87% reduction in progression if given in those first 5 days.
https://www.vekluryhcp.com/?utm_id=iw_sa_11453738585_111635246813&utm_medium=cpc&utm_term=medicine+remdesivir&gclid=CjwKCAjwj42UBhAAEiwACIhADocodyE-OQCnF5PXs6x5nuFnH230Tc-4V3iFulmtEoxHgYAY1Tr7hhoCTOoQAvD_BwE&gclsrc=aw.ds
https://files.constantcontact.com/17b067e5501/04046d2f-51dc-490f-89e1-edb5c535eeb6.pdf?rdr=true

3-Monoclonal Rx-now just **Bebtelovimab**. in adults and pediatric patients (12 years of age and older weighing at least 40 kg) https://www.fda.gov/media/156152/download
https://pi.lilly.com/eua/bebtelovimab-eua-factsheet-hcp.pdf

4-Molnupiravir – a last option with 30% reduction in progression so less impressive but no renal issues or drug interactions. Be careful w woman of childbearing age and get that negative pregnancy test, and NOT authorized for those under 18.

https://onlinelibrary.wiley.com/doi/10.1002/jmv.28011

5-Avoid: let us not do harmful things

- No steroids
- No antibiotics
- No Ivermectin
- No fluvoxamine
- No Colchicine
- No zinc
- No high dose vitamin C

6-And remember isolation for the infected.

Avoid Steroids

- Overall progression to severe disease and hospitalization increased 6x if given in first week to those with SpO2≥94%. Mortality increased by 35% if given in first week to those with SpO2≥94%
  https://academic.oup.com/qjmed/advance-article/doi/10.1093/qjmed/hcab212/6339640

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- glucocorticoids (≥20mg/day prednisolone equivalent) associated with hospital admission (aOR 2.50), cardiac events (aOR 1.93),pulmonary embolism (aOR 2.78) and mortality (aOR 3.48,[1.77-6.86]) due to COVID-19 https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X(22)00270-1/fulltext?dgcid=raven_jbs_aip_email

Avoid Antibiotics (Azithromycin, Doxycycline, etc.)

- Multiple studies with no benefit (doxycycline)
  https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00310-6/fulltext

- Azithromycin has no meaningful effect on clinical course for outpatients with COVID-19
  https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00263-0/fulltext
  https://jamanetwork.com/journals/jama/fullarticle/2782166
  https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00461-X/fulltext

Early Inflammatory Lower Respiratory Hypoxic Phase-

1-Steroids at the right time in the right patient at the right dose. This is *after* the first week and in patients with oxygen saturations <94%. This gives us about a 17% mortality reduction
https://www.nejm.org/doi/full/10.1056/nejmoa2021436

2-Anticoagulation Guidelines from a number of organizations including ASH –
https://www.hematology.org/education/clinicians/guidelines-and-quality-care/clinical-practice-guidelines/venous-thromboembolism-guidelines/ash-guidelines-on-use-of-anticoagulation-in-patients-with-covid-19

3-Pulmonary support .

4-Maybe Remdesivir if early, not if they are on a ventilator (first 10 days from symptom onset)

5-Immune modulation: Tocilizumab, the IL6-R blocker and in some cases Baricitinib, but only if there is progression and benefits outweigh risks.

6-AVOID: unnecessary antibiotics and unproven therapies